

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representation of  
The original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

What is claimed is:

1. A method of making dosage forms, comprising the steps of:
- a) compressing a powder into a compressed dosage form in a compression module;
  - 5 b) transferring said compressed dosage form to a thermal cycle molding module;
  - c) molding a flowable material around said compressed dosage form in said thermal cycle molding module; and
  - d) hardening said flowable material so as to form a coating over said
- 10 compressed dosage form;
- wherein steps (a) through (d) are linked together such that essentially no interruption occurs between said steps.
2. The method of claim 1, wherein one or more of said steps is performed on a
- 15 continuous basis.
3. The method of claim 1, wherein one or more of said steps is performed on an indexing basis.
4. The method of claim 1, wherein said powder contains a medicant.
- 20 5. The method of claim 1, wherein said flowable material contains a medicant.
6. The method of claim 1, wherein steps (a) through (d) are performed
- 25 simultaneously, such that while coatings are being hardened on a first group of compressed dosage forms in step (d), flowable material is being molded around a second group of compressed dosage forms in step (c), a third group of compressed dosage forms are being transferred to said thermal cycle molding module in step (b), and a fourth group of compressed dosage forms are being formed in step (a).
- 30 7. The method according to claim 1, further comprises the steps of:
- f) forming an insert; and
  - g) embedding said insert in said powder prior to compressing said powder into a compressed dosage form.
- 35 8. The method according to claim 7, wherein at least one of said powder and flowable material comprises a first medicant and said insert comprises a second medicant.

9. The method according to claim 7, wherein said insert comprises a thermal setting material.

5 10. The method according to claim 1, wherein said flowable material comprises a polymer.

11. The method according to claim 1, wherein said flowable material comprises a material selected from the group consisting of sucrose-fatty acid esters; fats, waxes, fat-  
10 containing mixtures, sugars, and low-moisture polymer solutions.

12. The method according to claim 10, wherein said flowable material comprises a gelatin.

15 13. The method according to claim 1, wherein step (c) comprises the steps of:  
(i) molding a first flowable material around a first portion of said compressed dosage form; and  
(ii) molding a second flowable material around a second portion of said compressed dosage form.

20 14. The method according to claim 1, wherein a single motor drives steps (a) through (d).

25 15. A dosage form made by the method of claim 1.

16. A method of making dosage forms, comprising the steps of:

a) compressing a first powder into a compressed dosage form in a first compression module;

30 b) transferring said compressed dosage form to a thermal cycle molding module;

c) molding a flowable material around said compressed dosage form in said thermal cycle molding module;

d) hardening said flowable material so as to form a coating over said compressed dosage form;

35 e) transferring said coated compressed dosage form to a second compression module; and

f) compressing a second powder around said coated compressed dosage form in said second compression module to form a compressed, coated, compressed dosage form;  
wherein steps (a) through (f) are linked together such that essentially no interruption  
5 occurs between said steps.

17. The method of claim 16, wherein one or more of said steps is performed on a continuous basis.

10 18. The method of claim 16, wherein one or more of said steps is performed on an indexing basis.

19. The method of claim 16, further comprising the steps of:

15 g) transferring said compressed, coated, compressed dosage form to a second thermal cycle molding module;

h) molding a second flowable material around said compressed, coated, compressed dosage form in said second thermal cycle molding module;

i) hardening said flowable material so as to form a second coating over said dosage form.

20 20. A method of making a dosage form, comprising the steps of:

a) forming an insert;

b) transferring said insert to a thermal cycle molding module;

25 c) molding a flowable material around said insert in said thermal cycle molding module; and

d) hardening said flowable material so as to form a coating over said insert;  
wherein steps (a) through (d) are linked together such that essentially no interruption occurs between said steps.

30 21. The method of claim 20, wherein said insert is formed in a thermal setting molding module.

22. The method of claim 20, wherein one or more of said steps is performed on a continuous basis.

35 23. The method of claim 20, wherein one or more of said steps is performed on an indexing basis.

24. A method of making a dosage form, comprising the steps of:
- a) forming at least two inserts;
  - b) transferring said inserts to a thermal cycle molding module;
  - c) molding a flowable material around said inserts in said thermal cycle molding module; and
  - d) hardening said flowable material so as to form a coating over said inserts to form a dosage form comprising at least two inserts surrounded by a coating;
- wherein steps (a) through (d) are linked together such that essentially no interruption occurs between said steps.
25. The method of claim 24, wherein said inserts are formed in a thermal setting molding module.
26. The method of claim 24, wherein one or more of said steps is performed on a continuous basis.
27. The method of claim 24, wherein one or more of said steps is performed on an indexing basis.
28. A method of making dosage forms, comprising the steps of:
- a) forming an insert;
  - b) transferring said insert to a compression module;
  - c) compressing a powder around said insert into a compressed dosage form in a compression module;
- wherein steps (a) through (c) are linked together such that essentially no interruption occurs between said steps.
29. The method of claim 28, wherein said powder is compressed in two steps to form a bi-layer tablet.
30. The method of claim 28, wherein said powder contains a first medicant.
31. The method of claim 28, wherein said insert contains a second medicant.
32. The method of claim 28 wherein said insert is formed in a thermal setting molding module.

33. The method of claim 28 wherein said insert is formed in a thermal cycle molding module.

34. A linked apparatus for making dosage forms containing a medicant, comprising:

a) a compression module having means for forming compressed dosage forms by compressing a powder containing said medicant;

b) a transfer device having means for continuously transferring said compressed dosage forms from said compression module to a thermal cycle molding module; and

c) a thermal cycle molding module having means for continuously molding a coating of flowable material over said compressed dosage forms.

35. The apparatus according to claim 34, further comprising means for operating said compression module, said transfer device, and said thermal cycle molding module simultaneously, such that as coatings are being molded on a first group of compressed dosage forms in said thermal cycle molding module, said transfer device transfers a second group of compressed dosage forms to said thermal cycle molding module, and said compression module forms a third group of compressed dosage forms.

36. The apparatus according to claim 34, wherein said medicant is a first medicant, and said apparatus further comprises:

d) a thermal setting molding module having means for forming an insert containing a second medicant; and

e) means for embedding said insert into said compressed dosage form prior to molding said coating over said compressed dosage form in said thermal cycle molding station.

37. The apparatus according to claim 34, wherein said flowable material comprises a polymer.

38. The apparatus according to claim 34, wherein said flowable material comprises a material selected from the group consisting of sucrose-fatty acid esters; fats, waxes, fat-containing mixtures, sugars, carbohydrates, thermoplastic starch, and low-moisture polymer solutions.

39. The apparatus according to claim 37, wherein said flowable material comprises a gelatin.

40. The apparatus according to claim 34, wherein said means for continuously molding a coating over said compressed dosage forms comprises:

- (i) means for molding a first flowable material around first portions of said compressed dosage forms; and
- (ii) means for molding a second flowable material around second portions of said compressed dosage forms.

41. The apparatus according to claim 34, wherein (i) said compression module comprises a die table mounted for rotation about a first axis and having a plurality of die cavities disposed around the perimeter thereof, whereby rotation of said die table carries said die cavities around a first circular path, and (ii) wherein said thermal cycle molding module comprises a rotor mounted for rotation about a second axis and comprising a plurality of mold cavities disposed around the perimeter thereof, whereby rotation of said rotor carries said mold cavities around a second circular path.

42. The apparatus according to claim 41, wherein said transfer device comprises a flexible conveying means traversing around a third path, a first portion of said third path being coincident with said first circular path, and a second portion of said third path being coincident with said second circular path.

43. The apparatus of claim 34 further comprising a motor providing power to the compression module, transfer device, and thermal cycle molding module.

44. An apparatus for making dosage forms containing a medicant, comprising:

a) a first rotor comprising a plurality of die cavities disposed around the circumference thereof so as to be carried around a first circular path by said rotor, each of said die cavities having an opening for receiving powder and at least one punch mounted for displacement into said die cavity, whereby displacement of said punch into said die cavity compresses powder contained in said die cavity into a compressed dosage form;

b) a second rotor comprising a plurality of mold cavities disposed around the circumference thereof so as to be carried around a second circular path by said second rotor, each of said mold cavities capable of enclosing at least a portion of a compressed dosage form and capable of receiving flowable material so as to coat said portion of said compressed dosage form enclosed by said mold cavity; and

e) a transfer device for transferring compressed dosage forms from said first rotor to said second rotor, said transfer device comprising a plurality of transfer units guided around a third path, a first portion of said third path being coincident with said first circular path and a second portion of said third path being coincident with said second circular path.

5

45. The apparatus of claim 44 further comprising a heat source, a heat sink, and a temperature control system, said temperature control system comprising a tubing system disposed proximal to said mold cavities and connected to said heat source and said heat sink for circulating heat transfer fluid through said heat source, through said heat sink, and proximal to said mold cavities, such that said mold cavities may be heated and cooled by said heat transfer fluid.

10

T.03220" 5.6599660